

**SPECIAL PROCEDURES SUBMISSION**

PTO/SB/30 (09-03)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>Request for Continued Examination (RCE) Transmittal</b>  Address to: Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	<b>Application Number</b>	09/876,863
	<b>Filing Date</b>	October 12, 2001
	<b>First Named Inventor</b>	Caplan, M.
	<b>Art Unit</b>	1614
	<b>Examiner Name</b>	Weddington, K.
	<b>Attorney Docket Number</b>	2002834-0115

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application. Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. **(Submission required under 37 CFR 1.114)** Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

i. ☐ Consider the arguments in the Appeal Brief or Rely Brief previously filed on \_\_\_\_\_

ii. ☐ Other \_\_\_\_\_

b. ☒ Enclosed

i. ☐ Amendment/Reply

iii. ☒ Information Disclosure Statement (IDS)

ii. ☐ Affidavit(s)/Declaration(s)

iv. ☐ Other Note: References to follow by mail

2. **Miscellaneous**

a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of \_\_\_\_\_ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

b. ☐ Other \_\_\_\_\_

3. **Fees**

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

The Director is hereby authorized to charge the following fees, or credit any overpayments, to

a. ☒ Deposit Account No. \_\_\_\_\_

i. ☐ RCE fee required under 37 CFR 1.17(e)

ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)

iii. ☒ Other Petition fee for Petition under CFR 1.313(c)

b. ☐ Check in the amount of \$ \_\_\_\_\_ enclosed

c. ☐ Payment by credit card (Form PTO-2038 enclosed)

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED**

<b>Name (Print/Type)</b>	Monica R. Gerber	<b>Registration No. (Attorney/Agent)</b>	46,724
<b>Signature</b>	<i>Monica R. Gerber</i>	<b>Date</b>	April 5, 2004

**CERTIFICATE OF MAILING OR TRANSMISSION**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

<b>Name (Print/Type)</b>	Sandra Saccoccia	<b>Date</b>	April 5, 2004
<b>Signature</b>	<i>Sandra Saccoccia</i>		

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

***SPECIAL PROCEDURES SUBMISSION*****ATTORNEY DOCKET NO.: 2002834-0115****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Caplan, et al. Examiner: Weddington, K.  
Serial No.: 09/976,963 Art Unit: 1614  
Filing Date: September 23, 2003  
Title: CONDUCTANCE OF IMPROPERLY FOLDED PROTEINS THROUGH  
THE SECRETORY PATHWAY AND RELATED METHODS FOR  
TREATING DISEASE

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Certificate of Facsimile Transmission	
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Sandra Saccoccia	
Typed or Printed Name of person signing certificate	

Sir:

**STATEMENT**

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

**Type of Statement**

The present Information Disclosure Statement is:

- ☒ An *original* Information Disclosure Statement; or  
☐ A *supplemental* Information Disclosure Statement.

**Compliance with 37 CFR § 1.97**

The present Information Disclosure Statement is being filed:

- ☐ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:  
☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);

***SPECIAL PROCEDURES SUBMISSION***

- ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
  - ☐ Before the mailing of a first Office action on the merits; or
  - ☒ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
- ☐ Certifies that *either*:
    - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
    - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or
  - ☐ Includes herewith the fee set forth in § 1.17(p).

***SPECIAL PROCEDURES SUBMISSION***

- ☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:
- ☐ Certifies that *either*:
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
- ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; and
- ☐ Includes herewith the fee set forth in § 1.17(p).

**Content of the Information Disclosure Statement**

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☐ A copy of each cited reference not indicated with an asterisk is included;

***SPECIAL PROCEDURES SUBMISSION***

- ☐ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

- ☐ Copies of English translations of one or more non-English references are included.
- ☒ The present Information Disclosure Statement is being filed as a submission accompanying a Request for Continued Examination. The Request for Continued Examination, the PTO-1449, and the present Statement are being submitted by facsimile. Copies of the references will follow shortly by mail, along with a copy of the present Statement and PTO-1449.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☐ Does not contain non-English language citations;
- ☐ Does contain non-English language citations, of which the following is a concise explanation:
- ☐ Includes one or more translations of a non-English citation.

Remarks

***SPECIAL PROCEDURES SUBMISSION***

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b).


The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,

  
Monica R. Gerber  
Registration No. 46,724

Dated: April 5, 2004

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Form PTO-1449 (REV. 8-83)		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket: 2002834-0115		In re Application No. 09/976,963	
INFORMATION DISCLOSURE STATEMENT				Applicant: Caplan <i>et al.</i>			
				Filing Date: October 12, 2001		Group: 1614	
U. S. PATENT DOCUMENTS							
Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass		
	6,344,475	Caplan <i>et al.</i>	February 5, 2002	514	431		
	6,323,191	Harris <i>et al.</i>	November 27, 2001	514	169		
	6,093,567	Gregory <i>et al.</i>	July 25, 2000	435	320.1		
	6,015,828	Cuppoletti	January 18, 2000	514	397		
	5,985,824	Cheng <i>et al.</i>	November 16, 1999	514	2		
	5,981,714	Cheng <i>et al.</i>	November 9, 1999	530	388.2		
	5,942,493	Kutscher <i>et al.</i>	August 24, 1999	514	15		
	5,939,536	O'Riordan <i>et al.</i>	August 17, 1999	530	413		
	5,912,176	Wang	June 15, 1999	435	452		
	5,886,026	Hunter <i>et al.</i>	March 23, 1999	514	449		
	5,869,264	Horisberger <i>et al.</i>	February 9, 1999	435	7.1		
	5,866,319	Alizon <i>et al.</i>	February 2, 1999	435	5		
	5,861,259	Roberts <i>et al.</i>	January 19, 1999	435	7.1		
	5,834,421	Cheng <i>et al.</i>	November 10, 1998	514	2		
	5,384,128	Meezen <i>et al.</i>	January 24, 1995	424	450		
	5,750,571	Cheng <i>et al.</i>	May 12, 1998	514	557		
	5,707,855	Hancock <i>et al.</i>	January 13, 1998	435	252.33		
	5,734,023	Nag <i>et al.</i>	March 31, 1998	530	403		
	5,733,720	Olivo	March 31, 1998	435	5		
	5,674,898	Cheng <i>et al.</i>	October 7, 1997	514	557		
	5,763,263	Dehlinger	June 9, 1998	435	287		
	5,639,458	Olsson <i>et al.</i>	June 17, 1997	424	185.1		
	5,670,626	Cheng	September 23, 1997	530	388.5		
	5,602,110	Drumm <i>et al.</i>	February 11, 1997	514	47		
	5,434,086	Collins <i>et al.</i>	July 18, 1995	435	125		
	5,384,128	Meezan <i>et al.</i>	January 24, 1995	424	450		
	5,364,762	Dormmair <i>et al.</i>	November 15, 1994	435	7.24		
	4,866,072	Edwards <i>et al.</i>	September 12, 1989	514	291		
U. S. PATENT APPLICATIONS							
Examiner's Initials	Serial No. or Publication No.	Applicant	Filing Date				

Form PTO-1449 (REV. 8-83)		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket: 2002834-0115		In re Application No. 09/976,963	
<b>INFORMATION DISCLOSURE STATEMENT</b>				Applicant: Caplan <i>et al.</i>			
				Filing Date: October 12, 2001		Group: 1614	
<b>FOREIGN PATENT DOCUMENTS</b>							
Examiner's Initials	Document No.	Country	Date	Translation			
				Yes	No		
	WO 00/70949	PCT	30 November 2000				
	WO 00/24391	PCT	02 May 2000				
	WO 98/37878	PCT	03 September 1998				
	WO 95/12420	PCT	11 May 1995				
	WO 95/07933	PCT	23 March 1995				
	WO 95/05810	PCT	02 March 1995				
	WO 93/13768	PCT	22 July 1993				
Examiner's Initials	<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>						
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		Applicant: Caplan <i>et al.</i>	
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<b>INFORMATION DISCLOSURE STATEMENT</b>			
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	Cheek, T.R. "Calcium Regulation and Homeostasis", <i>Curr. Opin. Cell. Biol.</i> 3: 199-205, 1991.		
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		Filing Date: October 12, 2001	Group: 1614
<b>INFORMATION DISCLOSURE STATEMENT</b>			
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	Elmore, et al., "Comparative Tissue-Specific Toxicities of 20 Cancer Preventive Agents Using Cultured Cells from 8 Different Normal Human Epithelia", <i>In Vitro. Mol. Toxicol.</i> 14(3): 191-207, 2001.		
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